# Before the Department of Health and Human Services Food and Drug Administration Washington, D.C.

In Re: Petition for the Modification of	)		or See
21 C.F.R. § 101.93 to Include	)		
Structure/Function Claims with	)	Docket No	f :
Disclaimers that Eliminate Perceived	)		
Disease Connotations	)		:

# **CITIZEN PETITION**

American Longevity, Inc. ("AL"), by counsel, hereby submits this petition under Chapter 21, Sections 10.30 and 101.93 of the Code of Federal Regulations, requesting that the Commissioner of Food and Drugs modify 21 C.F.R. § 101.93, as explained below, to permit use of structure/function claims, currently not permitted because of implied, but not express, links to physiological mechanisms affected by disease (e.g., cholesterol, blood pressure, and blood sugar), if those claims are qualified to eliminate the disease treatment connotations. The change is an obvious, less speech restrictive alternative to claim suppression and will provide dietary supplement companies greater freedom to communicate to the public truthful information about the effects of nutrients on body structures and functions. That, in turn, will enhance consumers' freedom of informed choice in the dietary supplement marketplace.

FDA's Final Rule concerning structure/function claims establishes guidelines and procedures that allow dietary supplement manufacturers to make certain claims on the labels and in the labeling of their products without prior FDA approval or authorization if notification is given to the agency, the company has substantiation for the claims, and a statutorily mandated disclaimer is placed on the label. See, Regulations on Statements Made for Dietary Supplements Concerning the Effect of the Product on the Structure or Function of the Body, 65 Fed. Reg.

1000 (January 6, 2000) (codified at 21 C.F.R. § 101.93) ("Final Rule"). The claims allowed are those which "describe the role of a nutrient or dietary ingredient intended to affect the structure or function in humans or that characterize the documented mechanism by which a nutrient or dietary ingredient acts to maintain such structure or function..." 21 C.F.R. § 101.93(f); 21 U.S.C. § 343(r)(6). The Final Rule prohibits companies from making structure/function claims that can be construed as implying an effect on a specific disease or class of diseases. 65 Fed. Reg. at 1012. Such claims render a dietary supplement an unapproved new drug. Structure/Function claims that link a nutrient to a physiological mechanism affected by disease (e.g., cholesterol, blood pressure, or blood sugar) without an express disease reference (e.g., "Product X may help lower cholesterol") are not permitted without premarket approval but should be if the underlying disease connotation perceived by FDA is expressly disclaimed. Such qualified structure/function claims would enable important health information, now suppressed, to reach consumers. To that end, a new, modified rule is proposed herein.

#### I. ACTION REQUESTED

Under the Final Rule, any claim that may imply that a nutrient may have an effect on the characteristic signs or symptoms of a specific disease or class of diseases, using scientific or lay terminology, will render the claim a disease claim. 21 C.F.R. § 101.93(g)(2)(ii). Thus, structure/function claims which state a nutrient, through a certain metabolic pathway of normal function, may "lower cholesterol," "lower blood pressure," or "lower blood sugar levels," are not allowed to be placed on the label or in the labeling of a dietary supplement without FDA premarket drug approval, pursuant to 21 C.F.R. § 314 et seq.

Suppression of that information violates the First Amendment. The view that consumers may be misled by accurate information (65 Fed. Reg. at 1012) cannot overcome the strong First

Amendment presumption in favor of the free exchange of such information. See, 44 Liquormart v. Rhode Island, 517 U.S. 484, 503 (1996) ("The First Amendment directs us to be especially skeptical of regulations that seek to keep people in the dark for what the government perceives to be their own good"); Rubin v. Coors Brewing, 514 U.S. 476, 497 (1995) (citing Virginia State Board of Pharmacy v. Virginia Citizen's Consumer Council Inc., 425 U.S. 748, 769-70 (1976)). There is never a sound legal justification for denying the public access to the truth. Thompson v. Western States Medical Center, 535 U.S. 357, 375 (2002) (citing 44 Liquormart, supra, 517 U.S. at 503).

Thus, AL respectfully requests that the Commissioner modify the current regulation governing structure/function claims, 21 C.F.R § 101.93, to permit use of structure/function claims that link a nutrient to physiological mechanisms affected by disease (without referring to the disease) if the disease connotation perceived by FDA is expressly disclaimed. In this way, FDA will permit consumers to receive important health information and cause FDA to conform to the strictures of the First Amendment by allowing a broader range of structure/function claims to reach the public.

#### II. STATEMENT OF GROUNDS

#### A. Interest of the Parties

American Longevity, a California company, has been a leading marketer of human and animal dietary supplements and cosmetics for over six years. AL markets dietary supplement and personal care products ranging from vitamin and mineral supplements to skin care products. AL relies on the use of structure/function claims on its dietary supplement products to convey truthful nutritional information to its customers. Under current structure/function claim regulations, AL cannot inform consumers the truthful and nonmisleading fact that through

normal physiological regulatory mechanisms its five dietary supplements containing L-arginine reduce blood pressure or that its seven dietary supplements containing niacin (nicotinic acid) reduce cholesterol levels or that its eleven dietary supplements containing alpha-lipoic acid or chromium lower serum sugar levels. AL would like to inform the consumers of its products of each of those physiological effects. Some consumers must be mindful of those effects because a lowering of the relevant physiological function could impair their health. Others need to know because they may need to avoid the products while on prescription drugs that have the same effect. Still others, indeed most consumers, have a keen interest in comprehending, and a right to know, all physiological effects of nutrients and foods they ingest. In particular, AL would like to place on its labels and in its labeling the following claims (and associated disclaimers) for products containing the stated nutrient: "Niacin inhibits cholesterol synthesis in the liver, and therefore may lower cholesterol" (Disclaimer: "This product is not a treatment for hypercholesterolemia (i.e., sustained high cholesterol). Those who may have that disease should see a physician for diagnosis and treatment"); "L-Arginine is a nutrient that your body uses to make nitrous oxide, which relaxes blood vessels, and therefore may lower blood pressure" (Disclaimer: "This product is not a treatment for hypertension (i.e., sustained high blood pressure). Those who may have that disease should see a physician for diagnosis and treatment"); "Alpha-lipoic acid enhances the movement of blood sugar into cell interiors and may lower blood sugar levels" and "Chromium is an essential nutrient required for proper insulin function and therefore may lower blood sugar levels" (Disclaimer for use with each claim: "This product is not a treatment for hyperglycemia (i.e., sustained high blood sugar levels) or diabetes. Those who may have either disease should see a physician for diagnosis and treatment").

#### B. Nature of the Problem

1. The Current Structure/Function Claim Regulation Unconstitutionally Prohibits Dietary Supplement Manufacturers from Making Truthful Structure/Function Claims That Link a Nutrient to a Normal Metabolic Function that May Imply Disease, Even if the Connotation is Disclaimed

Under current FDA regulations, dietary supplement labels may carry, without FDA preapproval, "statements that describe the role of a nutrient or dietary ingredient intended to affect the structure or function in humans or that characterize the documented mechanism by which a nutrient or dietary ingredient acts to maintain such structure or function..." 21 C.F.R. § 101.93(f); 21 U.S.C. § 343(r)(6)(A). Those statements are allowed without prior FDA approval so long as the company notifies the agency of its intention to use the structure/function claim and includes a certification by a responsible official that the company possesses substantiation for the claim and that the claim is truthful and not misleading. Id. at § 101.93(a)(1-3); 21 U.S.C. § 343(r)(6). A product that carries a "disease claim," i.e., one that explicitly or implicitly concerns damage to an organ, part, structure, or system of the body such that it does not function properly or a state of health leading to such dysfunctioning, is regulated by FDA as a drug unless the disease claim is an FDA approved or allowed health claim. 21 C.F.R. § 101.93(g)(1). This citizen petition does not concern express disease claims. It is limited to structure/function claims that link a nutrient to a metabolic pathway of normal functioning (that may imply disease connotations through references to physiological mechanisms affected by disease) but do not make any express reference to a disease. It is thus limited to claims that may imply a link to disease but do not express it.

In FDA's Final Rule, the agency describes express disease claims as explicit statements concerning a supplement's effect on a disease, such as "Protective against the development of cancer," or "Reduces the pain and stiffness associated with arthritis." 65 Fed. Reg. at 1012. The

agency defined implied disease claims as those which "do not mention the name of a specific disease, but refer to identifiable characteristics of a disease from which the disease itself may be inferred." <u>Id.</u> According to the Final Rule, FDA was concerned that implied disease claims could be so thinly veiled as to render the differentiation between express and implied disease claims irrelevant.

FDA considers statements to be implied disease claims if they claim an effect on one or more signs or symptoms that are recognizable to health care professionals or consumers as being characteristic of a specific disease or of a number of diseases. <u>Id.</u> at 1015; 21 C.F.R. § 101.93(g)(2)(ii). Such claims include "lowers cholesterol," "reduces joint pain," "lowers blood pressure," and "lowers blood sugar." 65 Fed. Reg. at 1006, 1015, 1028. However, if properly qualified, the disease treatment connotation perceived by FDA can be eliminated. <u>See infra</u> at 12-16. Dietary supplement claims, such as "lowers cholesterol," "lowers blood pressure," or "lowers blood glucose levels," should be allowed to be placed on the labels and in the labeling labeling of dietary supplements, if qualified to eliminate disease connotations.

The Courts have clearly established that claims on the labels of dietary supplements are commercial speech, protected under the First Amendment. See, Pearson v. Shalala, 164 F.3d 650, 655 (D.C. Cir. 1999) ("Pearson I"). In Central Hudson Gas & Electric Corp. v. Public Service Commission of New York, 447 U.S. 557 (1980), the Supreme Court established four elements that the government must prove to justify a restriction on commercial speech.

In commercial speech cases, then, a four-part analysis has developed. At the outset, we must determine whether the expression is protected by the First Amendment. For commercial speech to come within that provision, it at least must concern lawful activity and not be misleading. Next, we ask whether the asserted governmental interest is substantial. If both inquiries yield positive answers, we must determine whether the regulation directly advances the governmental interest asserted, and whether it is not more extensive than is necessary to serve that interest.

Id. at 466. In the Final Rule, FDA specifically stated that it will consider claims such as "lowers cholesterol" and "promotes low blood pressure" to be disease claims, suppressible outright. 65 Fed. Reg. at 106, 1019. The agency stated that "FDA continues to believe that 'lowers cholesterol,' however qualified, is an implied disease claim." Id. at 1019. Those determinations are contrary to established First Amendment precedent because they make suppression a first resort, failing to adopt instead the obvious less speech restrictive alternative of the disclaimer advocated herein.

In <u>Pearson</u> I, our Court of Appeals held FDA's refusal to allow truthful, nonmisleading health claims, with appropriate disclaimers, a violation of the First Amendment. The <u>Pearson</u> I Court did not find the government's goals (protection of health and prevention of fraud) to fit reasonably with its chosen means (claim suppression). Instead, the Court held that the use of a disclaimer was the constitutionally preferable, less speech restrictive remedy. <u>Pearson</u> I, 164 F.3d at 657 (citations omitted).

Similarly, in this case, FDA is required to allow truthful structure/function claims that link nutrients to physiological mechanisms affected by disease so long as the claims can be qualified to eliminate the disease connotations FDA perceives. An appropriate disclaimer, in addition to being constitutionally mandated as an obvious, less restrictive alternative to outright suppression, will supply consumers with useful information they would otherwise not receive and, thus, assist them in making truly informed choices. As discussed <u>infra</u>, more complete information is necessary for consumers to make dietary choices they perceive to be in their own best interests.

# A. <u>Paternalistic Assumptions About Consumer Behavior Have Been Rejected by the</u> Courts

The structure/function claims AL seeks to use contain important nutrient effect information that has informational value aside from the FDA's hypothesized implied treatment connotations. Cholesterol, blood pressure, and blood sugar levels support normal physiological structures and functions of the body throughout life. One published study found that the most consistent predictors of healthy aging included low blood pressure and low serum glucose. Reed, DM, Foley, DJ, White LR, Heimovitz H, Burchfiel CM, Masaki K. Predictors of healthy aging in men with high life expectancies. Am J Public Health 1998 88(10):1463-68. For healthy people to consume substances that promote such conditions is thus wise independent of the therapeutic effects directly relevant to diseased populations. The American Heart Association has stated that "the lower your blood pressure is, the better." See, http://www.americanheart.org/presenter.jhtml?identifier=4643 (last visited March 1, 2004). Studies have also shown increased longevity associated with low cholesterol levels. See, NIH Guide: Physiology and Pathology of Low Cholesterol States, Volume 23, Number 15 (April 15, 1994). As such, claims about nutrients' normal physiological effects on cholesterol, blood pressure, and blood glucose, disclaimed to avoid any implied disease connotations perceived by FDA, would avoid suppression of intended and express structure/function relations. Even within the normal, non-diseased range of blood pressure, glucose, LDL and HDL cholesterol, lower levels are associated with longer and healthier life expectancies.

In addition, full disclosure of truthful information concerning normal physiological functions is important for consumers who need to avoid supplements that may lower cholesterol, blood pressure, and blood sugar levels, as excessively low levels of those functions may be deleterious to some otherwise healthy individuals. If the truthful effects of a supplement are

suppressed, such as a supplement's ability to act as part of normal physiological regulators of cholesterol, blood pressure, or blood sugar levels, FDA should be particularly concerned about consumers whose health may be jeopardized due to the claim suppression. Consumers must know the truthful structure/function effects of a dietary supplement so they can better perceive normal physiological effects of nutrients that occur whether a disease is present or not. Cholesterol, for example, is not a disease, is required for human life, and is regulated via different normal mechanisms, some of which involve nutrients. To reveal normal nutrient regulatory mechanisms is not to state an association with disease and, to the extent the statement may be perceived as implying a disease connotation, that implication can be disclaimed.

In 44 Liquormart v. Rhode Island, supra, 517 U.S. at 503, the Supreme Court reasoned that the "First Amendment directs us to be especially skeptical of regulations that seek to keep people in the dark for what the government perceives to be their own good." See also Rubin v. Coors Brewing, 514 U.S. 476 at 497; Virginia State Board of Pharmacy v. Virginia Citizen's Consumer Council Inc., 425 U.S. at 769-770 ("There is, of course, an alternative to this highly paternalistic approach. That alternative is to assume that this information is not in itself harmful, that people will perceive their own best interests if only they are well enough informed, and that the best means to that end is to open the channels of communication rather than to close them"); See also, Central Hudson, 447 U.S. 557 at 562 ("Even when advertising communicates only an incomplete version of the relevant facts, the First Amendment presumes that some accurate information is better than no information at all"); Pearson I, 164 F.3d at 655 (Court rejects government's argument that health claims lacking "significant scientific agreement" are inherently misleading and opines that such a notion suggests that "it would be as if the

consumers were asked to buy something while hypnotized, and therefore they are bound to be misled...We think this contention is almost frivolous...we reject it').

As will be discussed <u>infra</u>, allowance of properly tailored disclaimers on structure/function claims that disclaim a possible, implied disease connotation (due to reference to a molecule or process present both in healthy and in diseased populations) is not only constitutionally required in lieu of outright suppression, but it is also a course of action that will permit consumers to be better informed of the truthful effects of dietary supplements on normal physiological structures or functions of the body without being led to believe that the product is meant to replace one or more drugs as a treatment for disease. It is a necessary and sufficient solution to the problem of speech suppression, one that restricts far less speech than the agency's current approach. The current approach keeps the public ignorant of important normal physiological processes, sacrificing consumer understanding of health maintenance.

#### B. The Current Regulatory Scheme Violates the Third Prong of the Central Hudson Test

The third prong of the <u>Central Hudson</u> test requires that the regulation in question "directly advance the government interest asserted." 447 U.S. at 566. A regulation "may not be sustained if it provides only ineffective or remote support for the government's purpose." <u>Id.</u> at 564. The party seeking to uphold a restriction on commercial speech carries the burden of justifying it (<u>Bolger v. Youngs Drug Products Corp.</u>, 463 U.S. 60, 71 n.20 (1983)). That "burden is not satisfied by mere speculation or conjecture; rather, a governmental body seeking to sustain a restriction on commercial speech must demonstrate that the harms it recites are real and that its restriction will in fact alleviate them to a material degree." <u>Edenfield v. Fane</u>, 507 U.S. 761, 770 (1993). As such, "Courts have generally required the state to present tangible evidence that the commercial speech in question is misleading and harmful to consumers before they will find that

restrictions on such speech satisfy <u>Central Hudson</u>'s third prong." <u>See, Borgner v. Brooks</u>, 284 F.3d 1204, 1211 (11th Cir. 2002) (<u>citing Ibanez v. Florida Department of Business and Professional Regulation</u>, 512 U.S. 136, 147 (1994)).

Hudson. Instead of providing empirical evidence that the harms it recites are real, the agency only offers speculation, stating that "such claims may encourage consumers to self-treat for a serious disease without benefit of a medical diagnosis or treatment... caus[ing] consumers to substitute potentially ineffective products for proven ones, foregoing or delaying effective treatment for serious and life-threatening illnesses." Final Rule at 1001 and 1003. Id. at 1005 ("FDA strongly believes that the dissemination of [implied disease claims] increases the likelihood that consumers will believe that the supplements are intended to treat or prevent the diseases described in the labeling"). FDA's speculative assertions are insufficient to show that "the harms it recites are real" (Edenfield, 507 U.S. at 770) and that its restriction (outright suppression of structure/function claims which may include information on physiological mechanisms present in healthy and diseased populations) advances the government's interest in a "direct and material way." Id. at 767. As such, FDA has failed to meet its burden of proof under the third prong of Central Hudson.

FDA has also failed to prove with empirical evidence that suppression of the structure/function claims here in issue directly and materially advances its twin goals of eliminating fraud and protecting public health. It stands to reason that a public not educated concerning the physiological mechanisms of nutrients in regulating, for example, cholesterol, blood pressure, and blood sugar may be more apt to be misled about what dietary supplements can do and may be more apt to miscalculate what best to consume in the food, dietary

supplement, and drug markets. Moreover, the lack of truthful information on the known effects of dietary supplements may well endanger public health by causing one ignorant of the effects suppressed to fail to consume a healthier diet that includes particular nutrients.

# C. The Current Regulatory Scheme Violates the Fourth Prong of the Central Hudson Test

The fourth and final prong of the <u>Central Hudson</u> test requires the government to show that its proposed regulation is "no more extensive than necessary" to serve its interests. 447 U.S. at 566. Thus, "if the Government could achieve its interests in a manner that does not restrict speech, or that restricts less speech, the Government must do so." <u>Thompson v. Western States Medical Center</u>, 535 U.S. 357, 371 (2002). FDA's disallowance of truthful structure/function claims that may imply, but do not express, a link to physiological mechanisms affected by disease, violates the fourth prong of the <u>Central Hudson</u> test because there is an obvious, less speech restrictive alternative to suppression: allowance of the claim with disclaimers designed to eliminate a possible disease connotation.

## 1. The Disclaimer Approach

As discussed <u>supra</u>, the <u>Pearson</u> I Court held that when potentially misleading commercial speech is in issue, "the preferred remedy is more disclosure, rather than less" (<u>Pearson</u> I, 164 F.3d at 657 (<u>citing Bates v. State Bar of Arizona</u>, 433 U.S. 350, 376 (1977)) and that "disclaimers [are] constitutionally preferable to outright suppression." <u>Pearson</u> I, <u>Id.</u> at 657 (<u>citing Peel v. Attorney Registration and Disciplinary Comm'n of Illinois</u>, 496 U.S. 91, 110 (1990); <u>In Re R.M.J.</u>, 455 U.S. 191, 206 n.20 (1982); <u>Shapero v. Kentucky Bar Association</u>, 486 U.S. 466, 478 (1988)).

Because no structure/function claim linking a dietary supplement to physiological mechanisms affected by disease (but not to a disease itself) admits of only one meaning (the

implied disease treatment connotation perceived by FDA), it is certainly possible to disclaim the disease treatment connotation and preserve the structure/function effect connotation. For instance, it does not logically follow that a dietary supplement that may "lower cholesterol" is a treatment for sustained high cholesterol (i.e., hypercholesterolemia). If a supplement acts through normal physiological mechanisms to lower cholesterol, it may do so whether the person consuming the supplement has high, normal, or low cholesterol levels. The statement "lowers cholesterol" is merely a description of "the role of a nutrient or dietary ingredient intended to affect the structure or function in humans." 21 C.F.R. § 101.93(f). Properly disclaimed, "lowers cholesterol" can be limited to a structure/function claim connotation. For example, were one to accompany the claim, "Niacin inhibits cholesterol synthesis in the liver, and therefore may lower cholesterol," with the following disclaimer, the disease treatment connotation would be eliminated: "This product is not a treatment for hypercholesterolemia (i.e., sustained high cholesterol). Those who may have that disease should see a physician for diagnosis and treatment."

At worst, the unqualified claims "lowers cholesterol," "lowers blood pressure," and "lowers blood sugar" <u>could</u> lead some to believe the supplements treatments for disease, but a tailored disclaimer can disavow that connotation and preserve a structure/function effect meaning. <u>See e.g.</u>, <u>In Re R.M.J.</u>, 455 U.S. at 203 ("States may not place an absolute prohibition on certain types of potentially misleading information...if the information also may be presented in a way that is not deceptive"). The preferred remedy is a disclaimer. <u>Id.</u> ("The remedy...is not necessarily a prohibition but preferably a requirement of disclaimers or explanation.")(citations omitted).

<sup>&</sup>lt;sup>1</sup> It is important for people who have low cholesterol levels to know of the effects of the supplement, as lowering already low cholesterol levels may produce deleterious effects. See, Hypolipoproteinemia, The Merck Manual, Section 12, Chapter 157 (Second Home Ed.).

The same kind of disclaimer used for "lowers cholesterol" could be used for "lowers blood pressure" and "lowers blood sugar." AL's claim for the relationship between L-Arginine and lower blood pressure, "L-Arginine is a nutrient that your body uses to make nitrous oxide, which relaxes blood vessels, and therefore may lower blood pressure," could be disclaimed as follows: "This product is not a treatment for hypertension (i.e., sustained high blood pressure). Those who may have that disease should see a physician for diagnosis and treatment." Claims concerning the relationship between Alpha-Lipoic acid/Chromium and lower blood sugar, "Alpha-lipoic acid enhances the movement of blood sugar into cell interiors and may lower blood sugar levels," and, "Chromium is an essential nutrient required for proper insulin function and therefore may lower blood sugar levels," could each be disclaimed as follows: "This product is not a treatment for hyperglycemia (i.e., sustained high blood sugar levels). Those who may have that disease should see a physician for diagnosis and treatment."

As discussed <u>supra</u>, FDA believes that a claim such as "lowers cholesterol," however qualified, is an implied disease claim that must be suppressed. 65 Fed. Reg. at 1019. That decision conflicts with the holding in <u>Pearson I</u>, which required FDA to allow disclaimers, in lieu of suppression, for potentially misleading claims. <u>Pearson I</u>, 164 F.3d at 658 ("It is clear then, that when government chooses a policy of suppression over disclosure—at least where there is no showing that disclosure would not suffice to cure misleadingness—government disregards a 'far less restrictive' means'). While inherently misleading claims can unquestionably be banned outright, FDA would have to satisfy a very high burden to show that a potentially misleading claim could not be cured by disclaimer. <u>Id.</u> at 659-660 ("...[W]hile we are skeptical that the government could demonstrate with empirical evidence that disclaimers...would bewilder

consumers and fail to correct for deceptiveness, we do not rule out that possibility"). See also, Pearson v. Shalala, 130 F. Supp. 2d 105, 118 (D.D.C. 2001) ("Pearson II") (Court holds "that [FDA] must shoulder a very heavy burden if it seeks to totally ban a particular health claim"; Pearson v. Shalala, 141 F. Supp. 2d 105, 112 (D.D.C. 2001) ("Pearson III") (Court indicates that the FDA "must 'demonstrate with empirical evidence that disclaimers similar to [those] suggested ... would bewilder consumers and fail to correct for deceptiveness."") (citations omitted); See also, Whitaker v. Thompson, 248 F. Supp. 2d 1, 9 (D.D.C. 2002)

In the Final Rule FDA fails to justify its determination that structure/function claims with implied disease connotations cannot eliminate those connotations through use of disclaimers.

FDA believes that implied disease claims "may encourage consumers to self-treat for a serious disease without benefit of a medical diagnosis or treatment" and that "reliance on disease prevention claims may encourage consumers to feel sufficiently protected from developing serious diseases...that they delay or forego regular screening..." 65 Fed. Reg. at 1001. FDA further stated in the Final Rule that it "strongly believes that the dissemination of [disease claims] on dietary supplement labels increases the likelihood that consumers will believe that the supplements are intended to treat or prevent the diseases described in the labeling." Id. at 1005.

No empirical evidence exists to support those suppositions.

Justifications for the suppression of accurate information fail because disclosure can inform consumers that it is not appropriate to use the dietary supplements as disease treatments yet still apprise them of the truth about the effect of the supplement on body structures and functions.

The Supreme Court and our Court of Appeals have held that the First Amendment favors disclosure over suppression. See Peel v. Attorney Registration and Disciplinary Comm'n of

Illinois, 496 U.S. at 110; In Re R.M.J., 455 U.S. at, 206 n.20; Shapero v. Kentucky Bar Association, 486 U.S. at 478; See also Pearson I, 164 F.3d at 657. The courts have recognized that the government carries a very heavy burden to justify restrictions on the communication of truthful, and even potentially misleading, commercial speech. Thompson v. Western States Medical Center, 535 U.S. at 373 ("It is well established that 'the party seeking to uphold a restriction on commercial speech carries the burden of justifying it") (citing Edenfield v. Fane, 507 U.S. 761, 770 (1993); See also, Pearson I at 659-660. It is not enough for government to speculate that qualified structure/function claims will cause consumers to forego diagnosis and treatment with appropriate prescription drugs. Rather, FDA must prove that the harms it recites are real and that its chosen remedy, suppression of structure/function claims, alleviates proven harms to a material degree. FDA's Final Rule presents no such proof and its speculation is counterintuitive (presumes consumers too ignorant to comprehend qualified structure/function claims) and contrary to extant precedent. See, Rubin v. Coors, 514 U.S. at 487 ("[T]he Government carries the burden of showing that the challenged regulation advances the Government's interest 'in a direct and material way.' That burden 'is not satisfied by mere speculation or conjecture; rather, a governmental body seeking to sustain a restriction on commercial speech must demonstrate that the harms it recites are real and that its restriction will in fact alleviate them to a material degree") (citing Edenfield, 507 U.S. at 770-771); see also Pearson I, 164 F.3d at 656.

FDA may not suppress truthful claims which state a dietary supplement's effect on a natural physiological function (e.g., intermittently high, but not chronically high blood pressure; intermittently high, but not chronically high cholesterol; intermittently elevated, but not chronically elevated blood sugar levels) even if they may imply disease prevention or treatment.

Instead of prohibiting those claims, the agency must allow them, with reasonable and adequate tailored disclaimers to eliminate the disease treatment connotations it perceives. Disclosure over suppression is the governing rule and should be followed. <u>Pearson I</u>, 164 F.3d at 657, <u>supra</u>.

#### 2. Less Speech Restrictive Alternatives

In the Final Rule FDA stated that "permitting implied disease claims as structure/function claims would...conflict with the health claim scheme...which requires food and dietary supplement manufacturers to obtain health claim authorization before making a claim 'which expressly or by implication' characterized the relationship of a nutrient to a disease or health-related condition." 65 Fed. Reg. at 1014. As such, FDA asserts that any claim which links or may link a dietary supplement to a disease requires health claim authorization. Id.

Forcing companies that do not intend or desire to make disease prevention claims to submit health claim petitions for every structure/function claim that may imply disease treatment or prevention by linking a nutrient to physiological mechanisms affected by disease (but not disease itself) violates the fourth prong of Central Hudson, because there are obvious, less speech-restrictive alternatives. Pearson I, 164 F.3d at 658. To be sure, the difference in cost and time between a structure/function claim submission and a health claim submission is profound. A structure/function claim for a dietary supplement may be made by a company without prior restraint but with simple notice to the agency no later than 30 days after the product with the claim is first marketed. See, 21 C.F.R. § 101.93(a)(1-3). By contrast, a health claim petition must satisfy a high threshold burden of proof to obtain FDA consent to lifting the prior restraint on such claims. The health claim prior restraint is not lifted until a company submits a detailed health claim petition to FDA, including, inter alia: all publicly available scientific evidence on the nutrient-disease relationship and considerable technical information to satisfy the various

factors contained in 21 C.F.R. §§ 101.14 and 101.70. A health claim submission is thus costly and time-consuming, a far greater restriction on speech than is imposed by the simple structure/function claim notification requirement.

In Thompson v. Western States, cited supra, the Supreme Court held that "if the Government could achieve its interests in a manner that does not restrict speech, or restricts less speech, than the Government must do so." 535 U.S. at 371. The burden imposed here comes in the form of a prior restraint, a complex regulatory scheme, and the costs associated with satisfying the regulatory requirements. See, Simon & Schuster, Inc. v. Members of the New York State Crime Victims Board, 502 U.S. 105, 115 (1991) ("A statute is presumptively inconsistent with the First Amendment if it imposes a financial burden on speakers because of the content of their speech"). In this case, FDA can more than adequately achieve its interests in protecting public health and preventing fraud by allowing truthful structure/function claims that link a nutrient to physiological mechanisms affected by disease by requiring disclaimers to eliminate the disease treatment connotation it perceives. Such a course of action would allow dietary supplement companies the freedom they need to convey truthful information to the public concerning a supplement's effect on normal physiological functions. FDA's prohibition on such qualified structure/function claims, effectively barring them from the market, violates controlling First Amendment precedent.

## III. ENVIRONMENTAL IMPACT

The requested action will not result in the introduction of any substance into the environment and is thus categorically excluded under the provisions of 21 C.F.R. §25.30.

### IV. CONCLUSION

AL respectfully requests that the Commissioner of Food and Drugs act at the earliest possible moment to publish in the Federal Register a notice of proposed rulemaking. That notice would propose to modify 21 C.F.R. § 101.93 to allow structure/function claims that expressly link a nutrient to physiological mechanisms affected by disease, but not to disease itself, provided that the claims are qualified to eliminate the disease treatment connotations FDA perceives. AL urges FDA to amend the following relevant sections of the structure/function claim regulation to read (with modifications presented in **bold**) as follows:

Sec 101.93: Certain types of statements for dietary supplements

- (c) Text for Disclaimer.
- (c)(3) Where there are statements made in accordance with section 403(r)(6) of the act that expressly associate a dietary supplement with a physiological mechanism affected by disease but not with a disease itself, those statements must be accompanied by an additional disclaimer which shall state:

This product is not a treatment for [the disease]. Those who may have that disease should see a physician for diagnosis and treatment.

- (d) Placement. The disclaimer shall be placed adjacent to the statement with no intervening material or linked to the statement with a symbol (e.g., an asterisk) at the end of each such statement that refers to the same symbol placed adjacent to the disclaimer specified in paragraphs (c)(1), (c)(2), or (c)(3) of this section. On product labels and in labeling (e.g., pamphlets, catalogs), the disclaimer shall appear on each panel or page where there is such a statement.
- (2) FDA will find that a statement about a product claims to diagnose, mitigate, treat, cure, or prevent disease (other than a classical nutrient deficiency disease) under 21 U.S.C. 343(r)(6) if it meets one or more of the criteria listed below. These criteria are not intended to classify as disease claims statements that refer to the ability of a product to maintain structure or function, unless the statement implies disease prevention or treatment and is not disclaimed in accordance with paragraph (c)(3) of this section. A statement claims to diagnose, mitigate, treat, cure, or prevent disease if it claims, explicitly, or implicitly without a disclaimer, that the product:
- (ii) Has an effect on the characteristic signs or symptoms of a specific disease or class of diseases, using scientific or lay terminology; unless the statement is made in accordance with paragraph (c)(3) of this section.

# V. CERTIFICATION

The undersigned certifies that, to his best knowledge and belief, this petition includes all information and views on which the petition relies, and that it includes representative data and information known to the petitioner, none of which is unfavorable to the petition.

Respectfully submitted, American Longevity, Inc.

Jonathan W. Emord

Claudia A. Lewis-Eng

Andrea G. Ferrenz

Jonathan R. Goodman

Kathryn E. Balmford

Counsel to American Longevity, Inc.

Emord & Associates, P.C. 5282 Lyngate Court Burke VA, 22015 (202) 466-6937- Phone (202) 466-6938- Fax

E-mail: jemord@emord.com

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